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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/779,187	02/08/2001	Patrick J. Muraca	5568/1070	5622

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EXAMINER

BEISNER, WILLIAM H

ART UNIT PAPER NUMBER

1744

DATE MAILED: 03/13/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/779,187

Applicant(s)

MURACA, PATRICK J.

Examiner

William H. Beisner

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Pre. Amd. filed 6/12/01 and 6/21/01.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 11-40 is/are pending in the application.
- 4a) Of the above claim(s) 33-40 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 11-32 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 12 June 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 8.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 11-32, drawn to a stylet, classified in class 435, subclass 283.1.
 - II. Claims 33-38, drawn to mold halves for forming a stylet element, classified in class 249, subclass 160.
 - III. Claims 39-40, drawn to an injection molding method, classified in class 264, subclass 299.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions of Group III and Group I are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the product as claimed can be made by another and materially different process, such as by machining a metal or plastic material rather than molding the material

3. Inventions of Group II and Group III are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this

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case the process as claimed can be practiced by another materially different apparatus, such as by using a mold which is different from that encompassed by the claims of Group II.

4. Inventions of Group II and Group I are related as apparatus and product made. The inventions in this relationship are distinct if either or both of the following can be shown: (1) that the apparatus as claimed is not an obvious apparatus for making the product and the apparatus can be used for making a different product or (2) that the product as claimed can be made by another and materially different apparatus (MPEP § 806.05(g)). In this case the product as claimed can be made by another and materially different apparatus, such as an apparatus which machines the product rather than molds the product.

5. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

6. During a telephone conversation with Paula Evans on 28 February 2003 a provisional election was made with preservation of right to traverse to prosecute the invention of Group I, claims 11-32. Affirmation of this election must be made by applicant in replying to this Office action. Claims 33-40 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Information Disclosure Statement

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7. The information disclosure statement filed 11 May 2001 has been considered and made of record.

Drawings

8. The corrected or substitute drawings were received on 12 June 2001. These drawings are acceptable.

Specification

9. The disclosure is objected to because of the following informalities:

Page 5 of the specification refers to a related application by attorney docket number. It is requested that this reference be updated to include the application number.

Appropriate correction is required.

Claim Objections

10. Claim 15 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form.

Claim 15 depends from claim 13 and recites a stylet diameter of at least 2mm while claim 13 recites a diameter range of 0.7mm to 5mm. Recitation of "at least 2mm" encompassed

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diameters which are greater than "5mm". As a result, the claim language of claim 15 does not include all of the limitations of the claim from which it depends.

Claim Rejections - 35 USC § 112

11. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

12. Claims 19 and 23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 19, "said non-stick surface" lacks antecedent basis. Note claim 19 depends from claim 13 not claim 18.

In claims 23, "said stylet tube" lacks antecedent basis. Note claim 23 depends from claim 17 not claim 22.

Claim Rejections - 35 USC § 102

13. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

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14. Claims 11-20, 22, 23, 26, 27, 30, 31 and 32 are rejected under 35 U.S.C. 102(e) as being anticipated by Leighton (US 6,103,518).

The reference of Leighton discloses a stylet (32) which includes a push surface (See Figure 2e) and a connecting end for connecting to a stylet body (34). The stylet body (34) includes a lumen for receiving the connecting end of the stylet (See Figure 2a). With respect to the material of the stylet pushing surface, the reference discloses that the stylet can be made of surgical steel or Teflon coated plastic (See column 8, line 35-46). These are materials recited in the instant specification which meet the required function recited in claim 11 of "maintain a temperature from -20° to 4° C during the process". With respect to the claimed prevention of rotation, as shown in Figure 2a, the stylet (32) is inherently mounted within body (34) without lateral or rotational movement, if not, the stylet (32) would not be capable of forcing the tissue sample out of the coring needle by pushing.

With respect to the dimensions of the coring needle and stylet of claims 12-16, see column 7, lines 19-29, which recites diameters of the coring needle as 0.4-4.0mm, preferably 0.3-2.0mm and a stylet diameter slightly smaller than the diameter of the coring needle.

With respect to the materials of the stylet of claims 17-19, see column 8, lines 35-46, which disclose surgical steel and Teflon coated polyvinyl chloride.

With respect to claim 20, the reference discloses that the stylet hub or body is made of brass (See column 11, lines 40-43).

With respect to claim 21, element 33 meets the limitations of the claimed base while element 34 meets the limitations of the claimed cap.

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With respect to claims 22 and 23, element 35 meets the limitations of the claimed stylet tube.

With respect to claims 26, 27, 30, 31 and 32, as shown in Figure 3, the stylet body includes an opening or joining section for receiving graspable element or dowel (39, 45) (See column 14, lines 9-22).

Claim Rejections - 35 USC § 103

15. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

16. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

17. Claims 21, 24 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Leighton (US 6,103,518) in view of Smith (US 5,515,861).

The reference of Leighton has been discussed above.

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The above claims differ by reciting that the stylet body includes a base and cap member wherein the base and cap are movable with respect to one another and include a resilient means (spring) provided between the base and cap.

The reference of Smith discloses a manually actuated tissue extraction device which includes a stylet (34); a stylet cap (38) for receiving the connecting end of the stylet (34); and a base (12) for slideably moving along the length of the stylet (34). The base (12) and cap (38) are separated by a spring (28).

In view of this teaching, it would have been obvious to one of ordinary skill in the art to employ the cannula (31) and stylet (32) of the reference of Leighton in a device as disclosed by the reference of Smith for the known and expected result of providing a device which is capable of manual operation while having the properties of the cannula and stylet of the primary reference of Leighton. The reference of Smith discloses that the manual actuated device can be used to extract tissue samples from strips of tissue or paraffin embedded tissue which is the same function required of the device of the primary reference. Manual actuation of the stylet device would allow the device to be used to extract tissue in the absence of the automated device of the primary reference of Leighton.

18. Claim 28 is rejected under 35 U.S.C. 103(a) as being unpatentable over Leighton (US 6,103,518) in view of Smith (US 5,515,861) and Gwinn (US 3,689,595).

The combination of the references of Leighton and Smith has been discussed above.

The above claim differs by reciting that the body of the device is constructed of a "plastic that withstands low temperature impact forces".

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The reference of Smith discloses that the components of the device can be manufactured of a high impact plastic (See Column 2, lines 52-55).

The reference of Gwinn discloses that high impact polypropylenes are known and are known to be impact resistant at low temperatures (See the abstract).

In view of these teachings, it would have been obvious to one of ordinary skill in the art to construct the stylet elements of the device of the modified primary reference using a high impact polypropylene for the known and expected result of providing an alternative means recognized in the art to achieve the same result, use of a known high impact plastic in place of a metal material as suggested by the reference of Smith.

19. Claim 29 is rejected under 35 U.S.C. 103(a) as being unpatentable over Leighton (US 6,103,518) in view of Smith (US 5,515,861), Gwinn (US 3,689,595) and Fawzi et al. (US 6,036,698).

The combination of the references of Leighton, Smith and Gwinn has been discussed above.

While the combination of the references of Leighton, Smith and Gwinn suggest the use of high impact polypropylene as a construction material, the above claim differs by reciting that the material of construction of the body is a mineral reinforced polypropylene.

The reference of Fawzi et al. discloses that it is known in the art to construct elements of a tissue removal instrument out of reinforced polymers (See column 5, lines 51-60).

In view of this teaching and in the absence of a showing of criticality and/or unexpected results, it would have been obvious to one of ordinary skill in the art to employ a reinforced

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polymer, including reinforced polypropylene, for the known and expected result of providing a material of construction which is stronger than regular polymers, thus increasing the structural integrity of the components of the device.

Conclusion

20. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

The references of Shaw (US 2,623,521); Jamshildi (US 3,630,192); Gray (US 5,040,542) and Kanner et al.(US 5,392,790) are cited as prior art references which pertain to tissue extraction devices which include stylet members.

The reference of Sincock (US 5,190,169) is cited as a prior art reference which pertains to a talc-filled polypropylene material for a needle holding device.

The references of Cady (US 4,007,653) and Schaumleffel (US 2,615,245) are cited as prior art which pertains to core cutting devices with plug ejectors.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to William H. Beisner whose telephone number is 703-308-4006. The examiner can normally be reached on Tues. to Fri. and alt. Mon. from 6:40am to 4:10pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert J. Warden can be reached on 703-308-2920. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9310 for regular communications and 703-872-9311 for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0661.



William H. Beisner
Primary Examiner
Art Unit 1744

WHB

March 10, 2003